CHAIRMAN HENRY A. WAXMAN

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

to the

NATIONAL FOOD POLICY CONFERENCE

7 March 1990

I'd like to thank you for this opportunity to speak with you this morning about the food safety issues you are most concerned about.

As we begin the 1990's, it is useful look back to the last decade and ask, How have things changes? What have we accomplished? Where are we going?

Of course, in terms of federal health and safety regulation, the most important event was the election of Ronald Reagan in 1980. Mr. Reagan came into office at a time when the federal government was the leader in insuring the safety of foods, as well as most other consumer products. In most areas, the states could have set their own standards, but they didn't, largely because people assumed that the federal government was doing a good job.

But President Reagan entered office committed to deregulation, a codeword for an agenda that would lead to less enforcement of the laws administered by the primary health and safety agencies – the Food and Drug Administration, the Environmental Protection Agency, and the Consumer Product Safety Commission. Budgets were cut. Essential scientific personnel fled government service.

In the early 1980's concerted efforts were made to permanently change the laws. Those were the years when massive and debilitating rewrites of the food safety laws were proposed -- when industry was exerting enormous resources to repeal the Delaney clause. Fortunately, these efforts did not succeed, but threats to food safety appeared elsewhere.

Simultaneously, the Reagan Administration attacked health and safety initiatives on three other fronts. First, it abandoned a large number of important consumer initiatives that were in place. For example, despite years of study and planning, the FDA's proposal to included patient package inserts in all prescription drugs was immediately ditched. The end of such programs eliminated any possibility for new consumer initiatives in other areas. The Administration refused to require mandatory labeling of salt in foods, and mandatory nutrition labeling wasn't even a possibility.

Second, the Reagan Administration instituted new levels of review which made it harder for agencies to issue regulations. The Office of Management and Budget was charged with reviewing all important regulations, and in the case of the Food and Drug Administration, the Secretary of the Department of Health an Human Services was given similar responsibilities. The result was an ironic one for an administration supposedly committed to streamlining the federal government.

OMB and HHS review has also tilted toward industry. Over the past ten years, those agencies were responsible for: (1) delaying a regulation requiring that aspirin labeled for Reye's Syndrome, a rare but often fatal disease that was killing hundreds of children each year; (2) reversing the FDA's decisions to remove six cancer-causing color additives from the market; (3) holding up FDA's decision by ban raw milk in interstate commerce because of the risk of salmonella. In each of these cases, the FDA did not act until forced to do so by consumer-group initiated lawsuits or Congressional oversight.

The third action taken by the Reagan Administration was to decrease enforcement. During the early 1980's, enforcement actions at the FDA dropped by about 50%; OSHA experienced the same dramatic decrease.

In the food area, this non-enforcement policy has its most dramatic effect in the regulation of health claims. Prior to 1984, there were virtually no health claims on foods. The FDA considered a claim that a food would prevent or help treat a particular disease to be a drug claim, and therefore prohibited such claims unless a manufacturer submitted evidence for review and approval under the drug approval requirements in the Food, Drug and Cosmetic Act. But as a result of the new non-enforcement policy, this process was ignored, and health claims have begun proliferating to the point where today, the situation is totally out of control.

This lack of enforcement places all the wrong pressures on industry. Responsible companies that on their own would not make misleading, unsupported health claims are pressured by the marketplace to do so. As a result, the least responsible companies set the standard with which all others must compete. In 1990, we find ourselves in a situation where the legal prohibition on including inaccurate or unsupportable information on food labels is largely unenforced. The FDA -- the agency responsible for protecting consumers from this type of fraud -- has lost control of the marketplace.

Meanwhile, something very interesting and very predictable is happening. Due in part to the legitimate concern arising from the EDB and ALAR contamination scares, consumers are demanding protection from their Government. They are demanding it from their state governments. And they are demanding it from their federal government. What is more, they are starting to get it.

At the state level, the most visible activity is in my own state of California. Several years ago, California enacted Proposition 65, which requires that food and other products containing carcinogens be labeled, unless the industry can demonstrate that there is no substantial risk to human health.

In the case of food in particular, it should not be necessary to label carcinogens. They should be banned. But where the federal government is not doing its job in protecting the food supply, then labeling is a second-best alternative. Proposition 65 is not the ideal approach to food regulation, but it does reflect the frustration of citizens who had started believing their President when he said he would cutback the federal agencies responsible for health and safety regulation. After all, Californians knew President Reagan better than anyone else, so it's not surprising that they were the first to take him seriously.

In November, Californians will vote on the "Big Green" initiative. One of its provisions is to phase out pesticides found by the Environmental Protection Agency to cause cancer. This is a more carefully focused approach, where the state relies on the federal government's scientific findings, but then adopts its own, tougher safety standard to protect its citizens. Early indications are that the initiative's prospects are excellent.

Meanwhile, the Attorney Generals in a number of states are acting to protect their citizens. They are bringing cases against food manufacturers for making false and misleading claims. Also, a number of localities have adopted ordinances to protect their citizens against pesticides.

Equally exciting is the new activity on the federal level. In fact, this may be a watershed year for federal food safety legislation. In past years, our Subcommittee has often concentrated on legislation pertaining to the regulation of drugs, vaccines and medical devices.

But this year food safety is a top priority. We are currently working on initiatives to: (1) tighten the regulation of pesticides; (2) require the Food and Drug Administration to adopt a mandatory fish inspection program; and (3) require mandatory nutrition labeling of foods and prohibit unproven health claims.

Each of these would give consumers new, important protections. The pesticide legislation would prohibit the use of pesticides on foods unless the residue leaves a negligible risk, which is defined as a risk of less than one in a million and one that is not likely to cause any adverse health effects such as cancer. Under current law, the EPA weighs the economic benefits of a pesticide to industry against the risk of the pesticide to consumers.

I have never thought that such a balancing made any sense. Indeed, I don't even understand how it can be done. And if it could be done, it's not right. Consumers should be protected from carcinogens and other hazards in the food supply, including those hazards caused by pesticides. They want that protection. They deserve it. And I am going to work to give it to them.

The fish bill is a product of the times. Currently, the regulation of food is divided between the FDA and the US Department of Agriculture. The USDA has the responsibility for inspecting meat and poultry. The FDA regulates all other foods, including fish.

Because of the hazards of meat and poultry, the USDA administers an extremely expensive and theoretically comprehensive program. Whereas the FDA spot checks foods such as fruits and vegetables, the USDA continuously inspects meat and poultry. As a result, the USDA's budget provides for as many resources to inspect meat and poultry as the entire FDA budget -- which the FDA must use for all foods, drugs, medical devices and all the other products it regulates.

Fish has fallen between the cracks. The FDA's legal authority is similar to the agency's authority to regulate adulterated corn. The agency can seize contaminated fish, but it has never adopted any regulations to set standards. While it has some inspection authority, that authority is inadequate. With respect to shellfish, it has established a program that depends on the cooperation of the states. It also coordinates its activities with the Department of Commerce, which has the responsibility for regulating fishing vessels.

Our Subcommittee recently reported out a bill which would require the FDA to establish a comprehensive program for the regulation of FDA. The agency would be required to adopt tight contamination standards and it would be given new enforcement authorities -- including the kind of inspection authorities that it has for prescription drugs, and new authority to impose civil penalties and to require a company to recall contaminated fish products.

It is heartening that there is broad support for a federal program to support the safety of fish. However, the prospects of a strong bill are seriously threatened by an unfortunate jurisdictional dispute -- the issue of whether the program should be administered by the FDA or the US Department of Agriculture.

The basic problem with placing authority at USDA has to do with that agency's mission. USDA is not a health regulatory agency. Instead its principal mission is to promote agriculture. Today it has regulatory duties with respect to meat and poultry, but we create a real and perceived risk of a conflict of interest when we ask a single agency to both promote and to regulate an industry.

Not surprisingly, the fish industry has generally supported placing jurisdiction in the Department of Agriculture. So have some members of the Agriculture Committees on Capitol Hill.

But what is surprising is that the consumer and labor community has split on the issue, making it more difficult for a strong consumer-oriented bill to pass Congress. The result is that Congress is not getting a clear message which unfortunately could lead to a weak bill that does not adequately assure the public safety.

Finally, let me say a few words about nutrition labeling and the problem of health claims on food.

Yet another legacy of the Reagan/Bush decade is that the public has lost confidence in the truthfulness of food labeling. Poll results recently released by the Washington Post concluded that "only 3 percent of Americans believe that food manufacturers never make misleading claims about the health benefits of their products." 60% of those surveyed believed that food statements were misleading either a lot or only a fair amount.

There was a time in America when health claims of the type we see daily on store shelves were illegal. But today food products can boast the absence of cholesterol while showering the consumers with globs of saturated fat. We have so-called Lite desert products in which the only lite component is the color of the icing. Cooking oil is now said to reduce cholesterol. Oat bran is being added to donuts and potato chips.

Clearly there is a place for accurate, scientifically based health claims to be made about food. But these claims must be carefully limited. They must be approved by the FDA. They must be based upon sound, objective science rather than the economic advantage of marketing.

There is growing recognition of the role that diet can play in reducing the risk of disease and promoting health. Everyone from the Surgeon General to the National Academy of Sciences is saying that we need less fat, sodium and cholesterol in our diets. Eating a healthy diet can reduce the risk of the nation's leading killers, heart disease and cancer.

But, if you rely upon today's food labels, following that advise is almost impossible. Most food products do not contain nutrition labeling. Of those that do, vital information like saturated fat or fiber content is missing. Some products labeled as containing multiple servings are ordinarily consumed at a single serving. The result is twice the labeled exposure to potentially unhealthy amounts of sugar or sodium.

The American public wants to follow the Surgeon General's advice. They want to choose foods that contribute to a healthy lifestyle. But when they try to look beyond the marketing hype they are greeted with a bewildering array of contradictory and misleading information. It is essential that the Congress and the FDA help the public get accurate information about the nutritional content of the food they consume and feed their families.

To do this Senator Metzenbaum and I have introduced legislation that would require accurate mandate nutrition labeling on all processed food. Special rules would be adopted to provide consumers with nutritional information on fish, fruits and vegetables. The FDA would determine the accuracy of health claims, and would require a sound scientific basis for suggesting any relationship between nutrients like fiber and illnesses like heart disease or cancer. Equally important, FDA will have to determine that the level of the nutrient is in sufficient quantity to have a beneficial effect. And, the legislation would prohibit claims like "No Cholesterol" when a product contained high levels of saturated fat.

In several respects the disease claim portions of the bill are similar to the FDA's recently issued "Proposed Regulations on Health Claims." While I applaud Secretary Sullivan for issuing the regulations, "proposed regulations" are no substitute for law. Federal legislation is needed to assure the public that FDA will do its job. We anticipate action on the bill later this month.

Protecting the American public's safety requires persistence and vigilance. Increased public awareness of food safety issues has helped keep valuable laws in place, and will hopefully provide the support we need to enact necessary new laws. All of you have done much to make this happen, and I look forward to working with you in the future.